K003663

JUN 2 8 2001

510(k) Summary of Safety and Effectiveness

Proprietary Name: Spacelabs Medical Anesthesia Delivery System (ADS) with Pressure Control Mode

Classification Name: Gas-Machine, Anesthesia, 73BSZ, 868.5160

Device Class: Class II

Manufacturer: Spacelabs Medical, Inc.
15220 NE 40th Street
Redmond, WA 98093

Establishment Registration Number: 3023361

Device to which substantial equivalence is claimed:

Spacelabs Medical Anesthesia Delivery System: K981530

Falcon Anesthesia System (Medical Industrial Equipment (MIE): K971030

Device Description:

The Spacelabs Medical Anesthesia Delivery System (ADS) [(K981530)] has been modified to include a Pressure Control Mode, an operating mode that allows for the controls to be set so that the patient is continually ventilated by the device using pressure as the control.

The Spacelabs Medical Anesthesia Delivery System, with Pressure Control Mode, is designed to deliver anesthetic gases in the hospital clinical environment for patients undergoing anesthesia in the induction, operating, or emergency room.

The System incorporates as valveless patient circuitry design that offers very low resistance during spontaneous breathing since it allows for the ebb and flow of natural breathing. Oxygen, nitrous oxide, and air are supplied to the gas distribution system for mixing with the selected anesthetic agent and delivery to the patient through the ventilation system. Another circuit separately provides for the cycling of patient expiration gases.

The delivery of gases is time cycled, volume or pressure controlled, pressure limited and monitored for alarm states and error messages. Additional user-selectable convenience features include a hold switch to permit the temporary cessation of mechanical (continual) ventilation to facilitate the taking of imagery (e.g., x-rays) and a "sigh" switch to provide extra volume above the

set tidal volume at a defined interval to allow for the more complete expiration of carbon dioxide.

The operator may select from three operating mode options: in the manual mode, where the patient can be ventilated manually via a hand bag or the patient can breathe spontaneously; the volume control mode, where the patient is continually ventilated by the device controlled by volume; the pressure control mode, where the patient is continually ventilated by the device controlled by pressure.

The delivery of gases is time cycled, volume or pressure controlled, pressure limited and monitored for alarm states and error messages. Additional user-selectable convenience features include a hold switch to permit the temporary cessation of mechanical (continual) ventilation to facilitate the taking of imagery (e.g., x-rays) and a "sigh" switch to provide extra volume above a set tidal volume at a defined interval to allow for the more complete expiration of carbon dioxide.

The control settings provide ease of use for both adult and pediatric patients in that the System may be set by the anesthesiologist for the appropriate tidal volume range, and pressure, based on patient needs.

The System uses standard, commercially available anesthesia system accessories appropriate to meet the needs of the clinician and patient.

Intended Use:

The Spacelabs Medical Anesthesia Delivery System with Pressure Control Mode is intended for the administration, continuously or intermittently, of general inhalation anesthetic gases and the maintenance of ventilation in both adult and pediatric patients. This is the same intended use of the Spacelabs Medical Anesthesia Delivery System cleared under K981530.

Substantial Equivalence:

The Spacelabs Medical Anesthesia Delivery System, cleared under 510(k) K981530, remains essentially the same, with an additional mode of operation, the Pressure Control Mode.

The Pressure Control Mode allows for the device controls to be set so that the patient is continually ventilated by the device using pressure. The Spacelabs Medical Anesthesia Delivery System with Pressure Control Mode will provide the operator with a choice of three operating modes: the manual mode, where the patient can be ventilated manually via a hand bag or the patient can breathe spontaneously; the volume control mode, where that patient is continually ventilated by the device controlled by volume; or the pressure control mode, where that patient is continually ventilated by the device controlled by pressure. The manual and volume control modes were previously cleared under K981530, while the pressure control mode is the subject of this submission.

The Spacelabs Medical Anesthesia Delivery System with the Pressure Control Mode is substantially equivalent to the Falcon Anaesthesia System marketed by Medical and Industrial Equipment Limited (MIE) [(510(k) reference K971030)]. The Falcon Anaesthesia System is also the same predicate device referenced in 510(k) K981580, under which the Spacelabs Medical Anesthesia Delivery System, without the Pressure Control Mode, was cleared.

The intended use, design, materials, accessories, energy source and principles of operation are similar to the Spacelabs Medical Anesthesia Delivery System and MIE's Falcon Anaesthesia System. All three Systems utilize a "bag in bottle" technology to provide fresh and anesthetic gases to control the ventilation cycle. All three Systems off the convenience for use in both adult and pediatric patients by user adjustment of the tidal volume range control to the appropriate mode setting. All three Systems are time cycled, volume or pressure controlled, and pressure limited at user selectable settings, generating alarms and error messages as appropriate.

The Spacelabs Medical Anesthesia Delivery System with Pressure Control Mode differs from the Falcon Anaesthesia System in offering a valveless patient circuitry to provide a low resistance pathway for delivery of fresh gas to the patient. The Spacelabs Medical Anesthesia Delivery System with Pressure Control Mode additionally features the capabilities for user selection of a "sigh" capability for more complete expiration of CO_2 gas, a "hold" feature to temporarily maintain a breath to reduce patient motion during an image taking session (e.g. x-ray), and the automated calculation and display of monitored parameters such as resistance and minute volume for user convenience.

Standards:

The Spacelabs Medical Anesthesia Delivery System with Pressure Control Mode is designed to meet the general safety requirements for medical equipment, including the requirements for UL2601-1, C222.2 No. 601-1, IEC 601-1 and IEC 601-1-2. The ADS also meets the requirements of industry

standards for anesthesia delivery systems including ASTM, EN and ISO Standards. The device will be CE marked as a Class IIB medical device to the Medical Device Directive.

Testing:

Qualification of the Spacelabs Medical Anesthesia Delivery System with Pressure Control Mode included risk analysis and functional testing. Environmental and electromagnetic capability testing performed in conjunction with Spacelabs Medical Anesthesia Delivery System K971030 address this new System as well.

The Spacelabs Medical Anesthesia Delivery System with Pressure Control Mode is as safe and effective as the predicate device and raises no new issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 8 2001

Mr. Al Von Houdt
Spacelabs Medical, Inc.
15220 N.E. 40th Street
P.O. Box 97013
Redmond, WA 98073-9713

Re: K003663
Spacelabs Medical Anesthesia Delivery System
Regulation Number: 868.5160
Regulatory Class: II (two)
Product Code: BSZ
Dated: April 16, 2001
Received: April 18, 2001

Dear Mr. Houdt:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this

response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1.2. INDICATIONS FOR USE

510(k) Number (if known): K003663

Device Name: Spacelabs Medical Anesthesia Delivery System

Indications for use:

The Spacelabs Medical Anesthesia Delivery System provides intermittent or continuous gas inhalation for adults and children (neonatal & pediatric). It allows the administration of operator selected gas mixtures of oxygen, nitrous oxide and air with any of the anesthetic agents: Halothane, Isoflurane, Enflurane, Desflurane or Sevoflurane. It provides safe and accurate gas flows to maintain patient respiration during anesthesia, and incorporates a ventilator, an oxygen monitor and a respiratory monitor. The ventilator provides the necessary power, as air or oxygen, to generate volumes and pressures in the ventilating system to ventilate a patient connected to the anesthesia machine. It is recommended for use only by trained physicians, in the operating room or similar surgical environments.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use

(Per 21 CFR 801.109)
(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K003663